General

Guideline Title

Urinary incontinence: the management of urinary incontinence in women.

Bibliographic Source(s)

National Collaborating Centre for Women's and Children's Health. Urinary incontinence: the management of urinary incontinence in women. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Sep. 48 p. (Clinical guideline; no. 171).

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: National Collaborating Centre for Women's and Children's Health. Urinary incontinence: the management of urinary incontinence in women. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Oct. 221 p.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Women's and Children's Health (NCC-WCH) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Since the publication of the 2006 guideline, new methods of managing urinary incontinence (UI) have become available on the National Health Service (NHS). Botulinum toxin A and sacral nerve stimulation are also now more commonly used for treating overactive bladder (OAB) symptoms. Synthetic tape procedures have become increasingly popular for the treatment of stress urinary incontinence (SUI), and there have been reported improvements in the effectiveness and advances in the types of procedure offered since 2006. Updated guidance is needed to reflect these changes. New recommendations for 2013 sit alongside the original recommendations from the 2006 guideline. It is important to emphasise that all of the 2006 recommendations are just as relevant and important now as they were when they were originally published.

Recommendations are marked as [new 2013], [2013], [2006] or [2006, amended 2013]:

- [new 2013] indicates that the evidence has been reviewed and the recommendation has been updated or added.
- [2013] indicates that the evidence has been reviewed but no change has been made to the recommended action
- [2006] indicates that the evidence has not been updated and reviewed since 2006
- [2006, amended 2013] indicates that the evidence has not been updated and reviewed since 2006, but changes have been made to the recommendation wording that change the meaning (see below)

The wording used in the recommendations in this guideline (for example words such as 'offer' and 'consider') denotes the certainty with which the recommendation is made (the strength of the recommendation) and is defined at the end of the "Major Recommendations" field.

Assessment and Investigation

History-Taking and Physical Examination

At the initial clinical assessment, categorise the woman's UI as SUI, mixed UI, or urgency UI/OAB. Start initial treatment on this basis. In mixed UI, direct treatment towards the predominant symptom. [2006]

If stress incontinence is the predominant symptom in mixed UI, discuss with the woman the benefit of conservative management including OAB drugs before offering surgery. [new 2013]

During the clinical assessment seek to identify relevant predisposing and precipitating factors and other diagnoses that may require referral for additional investigation and treatment. [2006]

Assessment of Pelvic Floor Muscles

Undertake routine digital assessment to confirm pelvic floor muscle contraction before the use of supervised pelvic floor muscle training for the treatment of UI. [2006, amended 2013]

Assessment of Prolapse

Refer women with UI who have symptomatic prolapse that is visible at or below the vaginal introitus to a specialist. [2006]

Urine Testing

Undertake a urine dipstick test in all women presenting with UI to detect the presence of blood, glucose, protein, leucocytes, and nitrites in the urine. [2006]

If women have symptoms of urinary tract infection (UTI) and their urine tests positive for both leucocytes and nitrites send a midstream urine specimen for culture and analysis of antibiotic sensitivities. Prescribe an appropriate course of antibiotic treatment pending culture results. [2006]

If women have symptoms of UTI and their urine tests negative for either leucocytes or nitrites send a midstream urine specimen for culture and analysis of antibiotic sensitivities. Consider the prescription of antibiotics pending culture results. [2006]

If women do not have symptoms of UTI, but their urine tests positive for both leucocytes and nitrites, do not offer antibiotics without the results of midstream urine culture. [2006]

If a woman does not have symptoms of UTI and her urine tests negative for either leucocytes or nitrites do not send a urine sample for culture because she is unlikely to have UTI. [2006]

Assessment of Residual Urine

Measure post-void residual volume by bladder scan or catheterisation in women with symptoms suggestive of voiding dysfunction or recurrent UTI. [2006]

Use a bladder scan in preference to catheterisation on the grounds of acceptability and lower incidence of adverse events. [2006]

Refer women who are found to have a palpable bladder on bimanual or abdominal examination after voiding to a specialist. [2006]

Referral

Urgently refer women with UI who have any of the following[1]:

- Microscopic haematuria in women aged 50 years and older
- Visible haematuria
- Recurrent or persisting UTI associated with haematuria in women aged 40 years and older
- Suspected malignant mass arising from the urinary tract [2006]

In women with UI, further indications for consideration for referral to a specialist service include:

- Persisting bladder or urethral pain

- Clinically benign pelvic masses
- Associated faecal incontinence
- Suspected neurological disease
- Symptoms of voiding difficulty
- Suspected urogenital fistulae
- Previous continence surgery
- Previous pelvic cancer surgery
- Previous pelvic radiation therapy[2] [2006]

Symptom Scoring and Quality-of-life Assessment

Use the following incontinence-specific quality-of-life scales when therapies are being evaluated: International Consultation on Incontinence Questionnaire (ICIQ), Bristol Female Lower Urinary Tract Symptoms (BFLUTS), Incontinence Quality of Life (I-QOL), Stress and Urgency Incontinence and Quality of Life Questionnaire (SUIQQ), Urinary Incontinence Severity Score (UISS), Stress-related leak, Emptying ability, Anatomy, Protection, Inhibition, Quality of life, Mobility, and Mental status (SEAPI-QMM) Incontinence Classification System, Incontinence Severity Index (ISI) and King's Health Questionnaire (KHQ)[3]. [2006]

Bladder Diaries

Use bladder diaries in the initial assessment of women with UI or OAB. Encourage women to complete a minimum of 3 days of the diary covering variations in their usual activities, such as both working and leisure days. [2006]

Pad Testing

Do not use pad tests in the routine assessment of women with UI. [2006]

Urodynamic Testing

Do not perform multi-channel cystometry, ambulatory urodynamics, or videourodynamics before starting conservative management. [2006, amended 2013]

After undertaking a detailed clinical history and examination, perform multi-channel filling and voiding cystometry before surgery in women who have:

- Symptoms of OAB leading to a clinical suspicion of detrusor overactivity, or
- Symptoms suggestive of voiding dysfunction or anterior compartment prolapse, or
- Had previous surgery for stress incontinence [2006, amended 2013]

Do not perform multi-channel filling and voiding cystometry in the small group of women where pure SUI is diagnosed based on a detailed clinical history and examination. [2006, amended 2013]

Consider ambulatory urodynamics or videourodynamics if the diagnosis is unclear after conventional urodynamics. [2006, amended 2013]

Other Tests of Urethral Competence

Do not use the Q-tip, Bonney, Marshall, and Fluid-Bridge tests in the assessment of women with UI. [2006]

Cystoscopy

Do not use cystoscopy in the initial assessment of women with UI alone. [2006]

Imaging

Do not use imaging (magnetic resonance imaging [MRI], computed tomography [CT], X-ray) for the routine assessment of women with UI. Do not use ultrasound other than for the assessment of residual urine volume. [2006]

Lifestyle Interventions

Caffeine

Recommend a trial of caffeine reduction to women with OAB. [2006]

Fluid Intake

Consider advising modification of high or low fluid intake in women with UI or OAB. [2006]

Weight

Advise women with UI or OAB who have a body mass index (BMI) greater than 30 to lose weight. [2006]

Physical Therapies

Pelvic Floor Muscle Training

Offer a trial of supervised pelvic floor muscle training of at least 3 months' duration as first-line treatment to women with stress or mixed UI. [2006]

Pelvic floor muscle training programmes should comprise at least 8 contractions performed 3 times per day. [2006]

Do not use perineometry or pelvic floor electromyography as biofeedback as a routine part of pelvic floor muscle training. [2006]

Continue an exercise programme if pelvic floor muscle training is beneficial. [2006]

Therapeutic Stimulation

Do not routinely use electrical stimulation in the treatment of women with OAB. [2006]

Do not routinely use electrical stimulation in combination with pelvic floor muscle training. [2006]

Electrical stimulation and/or biofeedback should be considered in women who cannot actively contract pelvic floor muscles in order to aid motivation and adherence to therapy. [2006]

Behavioural Therapies

Bladder Training

Offer bladder training lasting for a minimum of 6 weeks as first-line treatment to women with urgency or mixed UI. [2006]

Multicomponent Behavioural Therapy

If women do not achieve satisfactory benefit from bladder training programmes, the combination of an OAB drug with bladder training should be considered if frequency is a troublesome symptom. [2006]

Neurostimulation

Within this guideline neurostimulation covers transcutaneous sacral nerve stimulation (surface electrodes placed above the sacrum), transcutaneous posterior tibial nerve stimulation (surface electrodes place above the posterior tibial nerve), and percutaneous posterior tibial nerve stimulation (needles inserted close to the posterior tibial nerve).

Transcutaneous Sacral Nerve Stimulation

Do not offer transcutaneous sacral nerve stimulation[4] to treat OAB in women. [new 2013]

Transcutaneous Posterior Tibial Nerve Stimulation

Explain that there is insufficient evidence to recommend the use of transcutaneous posterior tibial nerve stimulation to treat OAB. [new 2013]

Do not offer transcutaneous posterior tibial nerve stimulation for OAB. [new 2013]

Percutaneous Posterior Tibial Nerve Stimulation

Do not offer percutaneous posterior tibial nerve stimulation for OAB unless:

- There has been a multidisciplinary team (MDT) review, and
- Conservative management including OAB drug treatment has not worked adequately, and
- The woman does not want botulinum toxin A[5] or percutaneous sacral nerve stimulation. [new 2013]

Explain that there is insufficient evidence to recommend the use of percutaneous posterior tibial nerve stimulation to routinely treat OAB. [new

2013]

Alternative Conservative Management Options

Absorbent Products, Urinals, and Toileting Aids

Absorbent products, hand held urinals, and toileting aids should not be considered as a treatment for UI. Use them only as:

- A coping strategy pending definitive treatment
- An adjunct to ongoing therapy
- Long-term management of UI only after treatment options have been explored [2006]

Catheters

Bladder catheterisation (intermittent or indwelling urethral or suprapubic) should be considered for women in whom persistent urinary retention is causing incontinence, symptomatic infections, or renal dysfunction, and in whom this cannot otherwise be corrected. Healthcare professionals should be aware, and explain to women, that the use of indwelling catheters in urgency UI may not result in continence. [2006]

Intermittent Urethral Catheters

Offer intermittent urethral catheterisation to women with urinary retention who can be taught to self-catheterise or who have a carer who can perform the technique. [2006]

Indwelling Urethral Catheters

Give careful consideration to the impact of long-term indwelling urethral catheterisation. Discuss the practicalities, benefits and risks with the patient or, if appropriate, her carer. Indications for the use of long-term indwelling urethral catheters for women with UI include:

- Chronic urinary retention in women who are unable to manage intermittent self-catheterisation
- Skin wounds, pressure ulcers, or irritations that are being contaminated by urine
- Distress or disruption caused by bed and clothing changes
- Where a woman expresses a preference for this form of management [2006]

Indwelling Suprapubic Catheters

Indwelling suprapubic catheters should be considered as an alternative to long-term urethral catheters. Be aware, and explain to women, that they may be associated with lower rates of symptomatic UTI, 'bypassing', and urethral complications than indwelling urethral catheters. [2006]

Products to Prevent Leakage

Do not use intravaginal and intraurethral devices for the routine management of UI in women. Do not advise women to consider such devices other than for occasional use when necessary to prevent leakage, for example during physical exercise. [2006]

Complementary Therapies

Do not recommend complementary therapies for the treatment of UI or OAB. [2006]

Preventive Use of Conservative Therapies

Offer pelvic floor muscle training to women in their first pregnancy as a preventive strategy for UI. [2006]

Women Who Choose Not to Have Further Treatment

If a woman chooses not to have further treatment for urinary incontinence:

- Offer her advice about managing urinary symptoms, and
- Explain that if she changes her mind at a later date she can book a review appointment to discuss past tests and interventions and reconsider her treatment options. [new 2013]

Pharmacological Treatment

General Principles When Using OAB Drugs

When offering antimuscarinic drugs to treat OAB always take account of:

- The woman's coexisting conditions (for example, poor bladder emptying)
- Use of other existing medication affecting the total anticholinergic load
- Risk of adverse effects [new 2013]

Before OAB drug treatment starts, discuss with women:

- The likelihood of success and associated common adverse effects, and
- The frequency and route of administration, and
- That some adverse effects such as dry mouth and constipation may indicate that treatment is starting to have an effect, and
- That they may not see the full benefits until they have been taking the treatment for 4 weeks [new 2013]

Prescribe the lowest recommended dose when starting a new OAB drug treatment. [new 2013]

If a woman's OAB drug treatment is effective and well-tolerated, do not change the dose or drug. [new 2013]

Choosing OAB Drugs

Do not use flavoxate, propantheline, and imipramine for the treatment of UI or OAB in women. [2006]

Do not offer oxybutynin (immediate release) to frail older women[6]. [new 2013]

Offer one of the following choices first to women with OAB or mixed UI:

- Oxybutynin (immediate release), or
- Tolterodine (immediate release), or
- Darifenacin (once daily preparation) [new 2013]

If the first treatment for OAB or mixed UI is not effective or well-tolerated, offer another drug with the lowest acquisition cost[7]. [new 2013]

Offer a transdermal OAB drug to women unable to tolerate oral medication. [new 2013]

For guidance on mirabegron for treating symptoms of overactive bladder, refer to the NGC summary of the NICE guideline Mirabegron for treating symptoms of overactive bladder (NICE technology appraisal guidance 290). [new 2013]

Reviewing OAB Drug Treatment

Offer a face-to-face or telephone review 4 weeks after the start of each new OAB drug treatment. Ask the woman if she is satisfied with the therapy:

- If improvement is optimal, continue treatment.
- If there is no or suboptimal improvement or intolerable adverse effects, change the dose, or try an alternative OAB drug (see related recommendations under "Choosing OAB Drugs," above), and review again 4 weeks later. [new 2013]

Offer review before 4 weeks if the adverse events of OAB drug treatment are intolerable. [new 2013]

Offer referral to secondary care if the woman does not want to try another drug, but would like to consider further treatment. [new 2013]

Offer a further face-to-face or telephone review if a woman's condition stops responding optimally to treatment after an initial successful 4-week review. [new 2013]

Review women who remain on long-term drug treatment for UI or OAB annually in primary care (or every 6 months for women over 75). [new 2013]

Offer referral to secondary care if OAB drug treatment is not successful. [new 2013]

If the woman wishes to discuss the options for further management (non-therapeutic interventions and invasive therapy) refer to the MDT and arrange urodynamic investigation to determine whether detrusor overactivity is present and responsible for her OAB symptoms:

- If detrusor overactivity is present and responsible for the OAB symptoms offer invasive therapy (see "Invasive Procedures for OAB," below).

- If detrusor overactivity is present but the woman does not wish to have invasive therapy, offer advice as described under "Women Who Choose Not to Have Further Treatment," above.
- If detrusor overactivity is not present refer back to the MDT for further discussion concerning future management. [new 2013]

Desmopressin

The use of desmopressin may be considered specifically to reduce nocturia[8] in women with UI or OAB who find it a troublesome symptom. Use particular caution in women with cystic fibrosis and avoid in those over 65 years with cardiovascular disease or hypertension. [2006, amended 2013]

Duloxetine

Do not use duloxetine as a first-line treatment for women with predominant stress UI. Do not routinely offer duloxetine as a second-line treatment for women with stress UI, although it may be offered as second-line therapy if women prefer pharmacological to surgical treatment or are not suitable for surgical treatment. If duloxetine is prescribed, counsel women about its adverse effects. [2006]

Oestrogens

Do not offer systemic hormone replacement therapy for the treatment of UI. [2006]

Offer intravaginal oestrogens for the treatment of OAB symptoms in postmenopausal women with vaginal atrophy. [2006]

The Multidisciplinary Team (MDT)

Inform any woman wishing to consider surgical treatment for UI about:

- The benefits and risks of surgical and non-surgical options
- Their provisional treatment plan
  Include consideration of the woman's child-bearing wishes in the counselling. [2006, amended 2013]

Offer invasive therapy for OAB and/or SUI symptoms only after an MDT review. [new 2013]

When recommending optimal management the MDT should take into account:

- The woman's preference
- Past management
- Comorbidities
- Treatment options (including further conservative management such as OAB drug therapy) [new 2013]

The MDT for urinary incontinence should include:

- A urogynaecologist
- A urologist with a sub-specialist interest in female urology
- A specialist nurse
- A specialist physiotherapist
- A colorectal surgeon with a sub-specialist interest in functional bowel problems, for women with coexisting bowel problems
- A member of the care of the elderly team and/or occupational therapist, for women with functional impairment [new 2013]

Inform the woman of the outcome of the MDT review if it alters the provisional treatment plan. [new 2013]

All MDTs should work within an established regional clinical network to ensure all women are offered the appropriate treatment options and high quality care. [new 2013]

Invasive Procedures for OAB

Botulinum Toxin A

After an MDT review, offer bladder wall injection with botulinum toxin A[5] to women with OAB caused by proven detrusor overactivity that has not responded to conservative management (including OAB drug therapy). [new 2013]

Discuss the risks and benefits of treatment with botulinum toxin A[5] with women before seeking informed consent, covering:

- The likelihood of being symptom free or having a large reduction in symptoms
- The risk of clean intermittent catheterisation and the potential for it to be needed for variable lengths of time after the effect of the injections has worn off
- The absence of evidence on duration of effect between treatments and the long-term efficacy and risks
- The risk of adverse effects, including an increased risk of urinary tract infection [new 2013]

Start treatment with botulinum toxin A[5] only if women:

- Have been trained in clean intermittent catheterisation and have performed the technique successfully, and
- Are able and willing to perform clean intermittent catheterisation on a regular basis for as long as needed [new 2013]

Use 200 units when offering botulinum toxin A[5]. [new 2013]

Consider 100 units of botulinum toxin A[5] for women who would prefer a dose with a lower chance of catheterisation and accept a reduced chance of success. [new 2013]

If the first botulinum toxin A[5] treatment has no effect discuss with the MDT. [new 2013]

If botulinum toxin A[5] treatment is effective, offer follow-up at 6 months or sooner if symptoms return for repeat treatment without an MDT referral. [new 2013]

Tell women how to self-refer for prompt specialist review if symptoms return following a botulinum toxin A[5] procedure. Offer repeat treatment as necessary. [new 2013]

Do not offer botulinum toxin B to women with proven detrusor overactivity. [2006]

Percutaneous Sacral Nerve Stimulation

Offer percutaneous sacral nerve stimulation to women after MDT review if:

- Their OAB has not responded to conservative management including drugs, and
- They are unable to perform clean intermittent catheterisation. [new 2013]

Consider percutaneous sacral nerve stimulation after MDT review if a woman's OAB has not responded to conservative management (including drugs) and botulinum toxin A[5]. [new 2013]

Discuss the long-term implications of percutaneous sacral nerve stimulation with women including:

- The need for test stimulation and probability of the test's success
- The risk of failure
- The long-term commitment
- The need for surgical revision
- The adverse effects [new 2013]

Tell women how to self-refer for prompt specialist review if symptoms return following a percutaneous sacral nerve stimulation procedure. [new 2013]

Augmentation Cystoplasty

Restrict augmentation cystoplasty for the management of idiopathic detrusor overactivity to women whose condition has not responded to conservative management and who are willing and able to self-catheterise. Preoperative counselling for the woman or her carer should include common and serious complications: bowel disturbance, metabolic acidosis, mucus production and/or retention in the bladder, UTI, and urinary retention. Discuss the small risk of malignancy occurring in the augmented bladder. Provide life-long follow-up. [2006, amended 2013]

Urinary Diversion

Urinary diversion should be considered for a woman with OAB only when conservative management has failed, and if botulinum toxin A[5], percutaneous sacral nerve stimulation and augmentation cystoplasty are not appropriate or are unacceptable to her. Provide life-long follow-up. [2006, amended 2013]

Surgical Approaches for SUI

When offering a surgical procedure discuss with the woman the risks and benefits of the different treatment options for SUI using the information in the "Information to facilitate discussion of risks and benefits of treatments for women with stress urinary incontinence" section of the original guideline document. [new 2013]

If conservative management for SUI has failed, offer:

- Synthetic mid-urethral tape (see "Synthetic Tapes," below), or
- Open colposuspension (see also "Colposuspension," below), or
- Autologous rectus fascial sling (see also "Biological Slings," below). [new 2013]

Synthetic Tapes

When offering a synthetic mid-urethral tape procedure, surgeons should:

- Use procedures and devices for which there is current high quality evidence of efficacy and safety[9].
- Only use a device that they have been trained to use (see "Maintaining and Measuring Expertise and Standards for Practice," below).
- Use a device manufactured from type 1 macroporous polypropylene tape.
- Consider using a tape coloured for high visibility, for ease of insertion and revision. [new 2013]

If women are offered a procedure involving the transobturator approach, make them aware of the lack of long-term outcome data. [new 2013]

Refer women to an alternative surgeon if their chosen procedure is not available from the consulting surgeon. [new 2013]

Use 'top-down' retropubic tape approach only as part of a clinical trial. [new 2013]

Refer to the NICE guideline Single-incision sub-urethral short tape insertion for stress urinary incontinence (NICE interventional procedure guidance 262) for guidance on single-incision procedures. [new 2013]

Offer a follow-up appointment (including vaginal examination to exclude erosion) within 6 months to all women who have had continence surgery. [new 2013]

Colposuspension

Do not offer laparoscopic colposuspension as a routine procedure for the treatment of stress UI in women. Only an experienced laparoscopic surgeon working in an MDT with expertise in the assessment and treatment of UI should perform the procedure. [2006]

Biological slings

Do not offer anterior colporrhaphy, needle suspensions, paravaginal defect repair, and the Marshall–Marchetti–Krantz procedure for the treatment of stress UI. [2006]

Intramural Bulking Agents

Consider intramural bulking agents (silicone, carbon-coated zirconium beads, or hyaluronic acid/dextran copolymer) for the management of stress UI if conservative management has failed. Women should be made aware that:

- Repeat injections may be needed to achieve efficacy
- Efficacy diminishes with time
- Efficacy is inferior to that of synthetic tapes or autologous rectus fascial slings [2006, amended 2013]

Do not offer autologous fat and polytetrafluoroethylene used as intramural bulking agents for the treatment of stress UI. [2006]

Artificial Urinary Sphincter

In view of the associated morbidity, the use of an artificial urinary sphincter should be considered for the management of stress UI in women only if previous surgery has failed. Life-long follow-up is recommended. [2006]

Considerations Following Unsuccessful Invasive SUI Procedures or Recurrence of Symptoms

Women whose primary surgical procedure for SUI has failed (including women whose symptoms have returned) should be:

- Referred to tertiary care for assessment (such as repeat urodynamic testing including additional tests such as imaging and urethral function studies) and discussion of treatment options by the MDT, or
- Offered advice as described under "Women Who Choose Not to Have Further Treatment," above, if the woman does not want continued invasive SUI procedures [new 2013]

Maintaining and Measuring Expertise and Standards for Practice

Surgery for UI should be undertaken only by surgeons who have received appropriate training in the management of UI and associated disorders or who work within an MDT with this training, and who regularly carry out surgery for UI in women. [2006]

Training should be sufficient to develop the knowledge and generic skills documented below. Knowledge should include the:

- Specific indications for surgery
- Required preparation for surgery including preoperative investigations
- Outcomes and complications of proposed procedure
- Anatomy relevant to procedure
- Steps involved in procedure
- Alternative management options
- Likely postoperative progress
  Generic skills should include:
    - The ability to explain procedures and possible outcomes to patients and family and to obtain informed consent
    - The necessary hand–eye dexterity to complete the procedure safely and efficiently, with appropriate use of assistance
    - The ability to communicate with and manage the operative team effectively
    - The ability to prioritise interventions
    - The ability to recognise when to ask for advice from others
    - A commitment to MDT working [2006]

Training should include competence in cystourethroscopy. [2006]

Operative competence of surgeons undertaking surgical procedures to treat UI or OAB in women should be formally assessed by trainers through a structured process. [2006]

Surgeons who are already carrying out procedures for UI should be able to demonstrate that their training, experience and current practice equates to the standards laid out for newly trained surgeons. [2006]

Only surgeons who carry out a sufficient case load to maintain their skills should undertake surgery for UI or OAB in women. An annual workload of at least 20 cases of each primary procedure for stress UI is recommended. Surgeons undertaking fewer than 5 cases of any procedure annually should do so only with the support of their clinical governance committee; otherwise referral pathways should be in place within clinical networks. [2006]

There should be a nominated clinical lead within each surgical unit with responsibility for continence and prolapse surgery. The clinical lead should work within the context of an integrated continence service. [2006]

A national audit of continence surgery should be undertaken. [2006]

Surgeons undertaking continence surgery should maintain careful audit data and submit their outcomes to national registries such as those held by the British Society of Urogynaecology (BSUG) and British Association of Urological Surgeons Section of Female and Reconstructive Urology (BAUS-SFRU). [2006]

Footnotes

[1]NICE's Referral guidelines for suspected cancer define urgent referral as the patient being seen within the national target for urgent referrals (currently 2 weeks).

[2]For further indications for consideration for referral, see recommendations under "Assessment of Prolapse" and "Assessment of Residual Urine."

[3]See full version of the original guideline document for details.

[4]This is often known as transcutaneous electrical nerve stimulation (TENS).

[5]At the time of publication (September 2013), most Botulinum toxin type A preparations did not have a UK marketing authorisation for this indication. Evidence was only available for the licensed Botulinum toxin A (BOTOX, Allergan) preparation.

[6]The Guideline Development Group defined 'frail older women' as those with multiple comorbidities, functional impairments such as walking or dressing difficulties, and any degree of cognitive impairment.

[7]This could be any drug with the lowest acquisition cost from any of the drugs reviewed, including an untried drug from under "Choosing OAB Drugs." The evidence review considered the following drugs: darifenacin, fesoterodine, oxybutynin (immediate release), oxybutynin (extended release), oxybutynin (transdermal), oxybutynin (topical gel), propiverine, propiverine (extended release), solifenacin, tolterodine (immediate release), tolterodine (extended release), trospium, and trospium (extended release). See Chapter 6 in the full version of the original guideline document for details (see the "Availability of Companion Documents" field).

[8]At the time of publication (September 2013), desmopressin did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Good practice in prescribing and managing medicines and devices for further information.

[9]The guideline only recommends the use of tapes with proven efficacy based on robust randomised controlled trial (RCT) evidence. However, technological advances are frequent, therefore the choice of tape should include devices that are shown in future clinical trials to have equal or improved efficacy at equal or lower cost. At the time of publication (September 2013) the following met the Guideline Development Group criteria: Tension-free vaginal tape (TVT) or Advantage for a 'bottom-up' retropubic approach Tension free vaginal tape-obturator (TVT-O) for an 'inside-out' transobturator approach Monarc and obtryx halo for an 'outside-in' transobturator approach.

Definitions:

Strength of Recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group (GDG) makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the GDG is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

Interventions That Must (or Must Not) Be Used

The GDG usually uses 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally 'must' (or 'must not') is used if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Interventions That Should (or Should Not) Be Used – a 'Strong' Recommendation

The GDG uses 'offer' (and similar words such as 'refer' or 'advise') when confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. Similar forms of words (for example, 'Do not offer…') are used when the GDG is confident that an intervention will not be of benefit for most patients.

Interventions That Could Be Used

The GDG uses 'consider' when confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

Note: NICE began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of 'The guidelines manual' (January 2009) (see the "Availability of Companion Documents" field). This does not apply to any recommendations ending [2006]. In particular, for recommendations labelled [2006] the word 'consider' may not necessarily be used to denote the strength of the recommendation.

Clinical Algorithm(s)

The following care pathways are included in the full version of the original guideline document (see the "Availability of Companion Documents"

field):

- Initial advice and conservative treatments
- Drug treatment for OAB and mixed UI
- Secondary care including urodynamic testing and MDT
- Surgical approaches for SUI
- Invasive approaches to OAB
- Referral for specialist intervention and surgeon standards
- Alternative conservative management and pharmacological options

In addition, a National Institute for Health and Care Excellence (NICE) pathway titled "Urinary Incontinence in Women Overview" is available from the NICE Web site .

Scope

Disease/Condition(s)

Urinary incontinence (UI) including:

- Stress UI
- Urgency UI
- Mixed UI
- Overactive bladder (OAB)

Note: This guideline does not address the management and treatment of co-morbidities, such as pelvic organ prolapse (POP), except where they relate to the treatment of UI and/or OAB syndrome; pelvic organ prolapse; incontinence caused by neurological disease; incontinence in men; incontinence in children and faecal incontinence.

Guideline Category

Diagnosis

Evaluation

Management

Treatment

Clinical Specialty

Family Practice

Geriatrics

Internal Medicine

Obstetrics and Gynecology

Physical Medicine and Rehabilitation

Surgery

Urology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Occupational Therapists

Patients

Physical Therapists

Physician Assistants

Physicians

Public Health Departments

Guideline Objective(s)

- To offer best practice advice on the care of women with urinary incontinence (UI)
- To provide guidance on:
    - Initial and ongoing assessments and investigations
    - Appropriate use of conservative and surgical treatment options
    - The competence required by surgeons performing the primary and subsequent operative procedures

Target Population

Women with urinary incontinence (UI) and/or overactive bladder (OAB) syndrome, their families and other carers

Interventions and Practices Considered

Diagnosis/Evaluation

1. History taking and physical examination
2. Assessment of pelvic floor muscles
3. Assessment of prolapse
4. Urine testing
5. Assessment of residual urine
6. Referral
7. Symptom scoring and quality of life assessment
8. Bladder diaries
9. Urodynamic testing, as indicated

Management/Treatment

1. Lifestyle interventions
    - Caffeine reduction
    - Modification of fluid intake
    - Weight loss
2. Physical therapies
    - Pelvic floor muscle training
    - Therapeutic stimulation (electrical stimulation and/or biofeedback)
3. Behavioral therapies
    - Bladder training

    - Multicomponent behavioural therapy
4. Neurostimulation (percutaneous posterior tibial nerve stimulation)
5. Catheters
    - Intermittent urethral
    - Indwelling urethral
    - Indwelling suprapubic
6. Absorbent products, urinals, and toileting aids
7. Pelvic floor muscle training
8. Pharmacological treatment
    - Discussion with patients about adverse effects of overactive bladder (OAB) drug treatment
    - Oxybutynin (immediate release)
    - Tolterodine (immediate release)
    - Darifenacin (once daily preparation)
    - Desmopressin
    - Duloxetine
    - Oestrogen
9. Multidisciplinary team (MDT) review
10. Invasive procedures for OAB
    - Botulinum toxin A
    - Percutaneous sacral nerve stimulation
    - Augmentation cystoplasty
    - Urinary diversion
11. Surgical approaches for stress urinary incontinence (SUI)
    - Synthetic tapes
    - Colposuspension (not recommended routinely)
    - Intramural bulking agents
    - Artificial urinary sphincter

Note: The following were considered but not recommended: pad testing; Q-tip, Bonney, Marshall and Fluid-Bridge tests; cystoscopy; multi-channel cystometry, ambulatory urodynamics, and videourodynamics before conservative management; magnetic resonance imaging (MRI); computed tomography (CT); ultrasound (other than for assessment of residual urine); transcutaneous sacral nerve stimulation; transcutaneous posterior tibial nerve stimulation; complementary therapies; flavoxate, propantheline and imipramine; systemic hormone replacement therapy; biological slings (colporrhaphy, needle suspensions, paravaginal defect repair, Marshall-Marchetti-Krantz procedure); autologous fat and polytetrafluoroethylene as intramural bulking agents.

Major Outcomes Considered

- Continence status (zero episodes per day)
- Self-reported rate of absolute symptom reduction
- Adverse effects
- Incontinence-specific quality of life
- Psychological outcomes, such as anxiety and depression
- Clinical measures, such as cystometric capacity, post-void residual volume

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Women's and Children's Health (NCC-WCH) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

See the full version of the original guideline document for the methodology for the 2006 version of this guideline.

Developing Review Questions and Protocols and Identifying Evidence

The Guideline Development Group (GDG) formulated review questions based on the topics agreed with the stakeholders and included in the scope (see Appendix A in the full version of the original guideline document) and prepared a protocol for each review question (see Appendix D in the full version of the original guideline document). These formed the starting point for systematic reviews of relevant evidence. Published evidence was identified by applying systematic search strategies (see Appendix E in the full version of the original guideline document) to the following databases: Medline (1950 onwards), EMBASE (1980 onwards), Cumulative Index to Nursing and Allied Health Literature (CINAHL; 1982 onwards), and three Cochrane databases (Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and the Database of Abstracts of Reviews of Effects). Searches to identify economic studies were undertaken using the above databases, the National Health Service (NHS) Economic Evaluation Database (NHS EED), and the Health Technology Assessment (HTA) database. None of the searches were limited by date. Searches in EMBASE were limited to English language, and searches in Medline were limited to English language and studies in humans. None of the other searches were limited by language of publication (although publications in languages other than English were not reviewed). Validated search filters were used to identify particular study designs, such as randomised controlled trials. There was no systematic attempt to search grey literature (conference abstracts, theses, or unpublished trials), nor was hand searching undertaken of journals not indexed on the databases.

Towards the end of the guideline development process, the searches were updated and re-executed to include evidence published and indexed in the databases by 30 November 2012.

Some studies were excluded from the guideline reviews after obtaining copies of the publications because they did not meet inclusion criteria specified by the GDG (see Appendix G in the full version of the original guideline document). These studies are listed in alphabetical order for each question and the reason for exclusion provided for each one.

Number of Source Documents

The number of studies identified for each clinical question is provided in Appendix F in the full guideline document (see the "Availability of Companion Documents" field).

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Overall Quality of Outcome Evidence in Grading of Recommendations Assessment, Development and Evaluation (GRADE)

Level	Description
High	Further research is very unlikely to change confidence in the estimate of effect.
Moderate	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
Low	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
Very Low	Any estimate of effect is very uncertain.

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Women's and Children's Health (NCC-WCH) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

See the full version of the original guideline document for the methodology for the 2006 version of this guideline.

Clinical Evidence

Reviewing and Synthesising Evidence

Evidence relating to clinical effectiveness was reviewed and synthesised according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. In the GRADE approach, the quality of the evidence identified for each outcome in the review protocol is assessed according to the factors listed below, and an overall quality rating (high, moderate, low, or very low) is assigned by combining the ratings for the individual factors.

- Risk of bias (in study design using either NICE or Critical Appraisal Skills Programme [CASP] methodological checklists; see http://www.nice.org.uk/guidelinesmanual and http://www.casp-uk.net/). This also includes limitations in the design or execution of the study (including concealment of allocation, blinding, loss to follow up; these can reduce the quality rating).
- Inconsistency of effects across studies – occurs when there is variability in the treatment effect demonstrated across studies (heterogeneity). (This can reduce the quality rating.)
- Indirectness – the extent to which the available evidence fails to address the specific review question (this can reduce the quality rating).
- Imprecision – present when there is uncertainty around the estimate of effect, for example when the confidence intervals are wide and cross the 'imaginary' lines of clinically significant effect (see "Outcome Measures" below). This reflects the confidence in the estimate of effect. (This can reduce the quality rating.)
- Other considerations (including large magnitude of effect, evidence of a dose–response relationship, or confounding variables likely to have reduced the magnitude of an effect; these can increase the quality rating in observational studies, provided no downgrading for other features has occurred).

The type of review question determines the highest level of evidence that may be sought. For issues of therapy or treatment, the highest possible evidence level is a well-conducted systematic review or meta-analysis of randomised controlled trials (RCTs), or an individual RCT. In the GRADE approach, a body of evidence based on RCTs has an initial quality rating of high, but this may be downgraded to moderate, low, or very low if the factors listed above are not addressed adequately. For issues of prognosis, the highest possible level of evidence is a controlled observational study (a cohort study or case–control study), and a body of evidence based on such studies would have an initial quality rating of low, which might be downgraded to very low or upgraded to moderate or high, depending on the factors listed above.

For each review question the highest available level of evidence was sought. Where appropriate, for example, if a systematic review, meta-analysis, or RCT was identified to answer a question directly, studies of a weaker design were not considered. Where systematic reviews, meta-analyses, and RCTs were not identified, other appropriate experimental or observational studies were sought. Within the full guideline, summary GRADE tables are presented. The full GRADE tables can be found in Appendix I in the full version of the original guideline document.

For the review in this update the Guideline Development Group (GDG) used the study types and methodology checklists shown in the table below.

Table. Study Types per Question and Corresponding NICE Methodological Checklist Used

Question	Study Type	Checklist
Botulinum toxin A	Randomised controlled trials	NICE checklist for randomised controlled trials
Neuromodulation	Randomised controlled trials	NICE checklist for randomised controlled trials

Question	Study Type	Checklist
Antimuscarinics	Systematic review	NICE checklist for systematic reviews and meta-analyses
Surgical interventions	Randomised controlled trials	NICE checklist for randomised controlled trials
	Observational studies	CASP checklist for observational studies

NICE, National Institute for Heath and Care Excellence; CASP, critical appraisal skills programme

The GDG used the CASP checklist for observational studies as none of the NICE checklists were appropriate for non-comparative studies.

The quality items for each study are reported the study's evidence table and are summarised in the footnotes of each GRADE profile. For this guideline, footnotes were inserted to explain the choice made while assessing the quality of evidence for each outcomes. These footnotes indicated if the GDG upgraded the evidence level, downgraded the evidence level, or left the evidence level unchanged, and gave the rationale for doing this.

Basic characteristics of each included study were summarised in evidence tables for each review question (see Appendix H in the full version of the original guideline document) along with the quality assessment. Where outcome data were presented in studies included in this guideline review, results were entered in text-boxes exactly as reported in the full-text report of the study. The data grids in the 'Results' column contain data exported to Revman 5.1 (see http://ims.cochrane.org/revman) for meta-analysis. Where the standard deviation (SD) of the mean change from baseline was not reported, this was imputed using either the baseline SD from the control group or the SD from a similar group.

Where possible, dichotomous outcomes were presented as relative risks (RRs) with 95% confidence intervals (CIs), and continuous outcomes were presented as mean differences with 95% CIs or SDs.

The body of evidence identified for each therapy or treatment review question (or part of a review question) was presented in the form of a GRADE evidence profile summarising the quality of the evidence and the findings (pooled relative and absolute effect sizes and associated CIs). Where possible, the body of evidence corresponding to each outcome specified in the review protocol was subjected to quantitative meta-analysis. In such cases, pooled effect sizes were presented as pooled risk ratios (RRs), pooled odds ratios (ORs), or mean differences. By default, meta-analyses were conducted using a random effects models as this is regarded as a more conservative method. Where quantitative meta-analysis could not be undertaken, the range of effect sizes reported in the included studies was presented in a GRADE profile.

Outcome Measures

For this guideline update, the effectiveness of interventions to treat urinary incontinence has been assessed against a variety of outcomes. The justification for using these outcomes is based on their relevance to women with the condition, to stakeholders involved in the consultation for this guideline and the expert consensus opinion of members of the multidisciplinary GDG. Outcomes included those that were felt to be desirable states (for example, improvement in continence status) and the unwanted side-effects of treatment (for example, the need for self-catheterisation). When assessing the effectiveness of a particular treatment, information about the effect of that treatment on one or more primary outcomes was sought (see the "Major Outcomes Considered" field).

Once the GDG was convened, each member was surveyed to reach agreement on how to measure outcomes in a clinically meaningful way. The GDG members were asked individually to consider the time-point at which a specific outcome should be measured and the important adverse effects, and to prioritise the outcomes. (The questionnaire and feedback are available in Appendix V in the full version of the original guideline document.)

Throughout the review, confidence intervals were used to decide imprecision, using a 'zone' rule (see Figure 1 in the full version of the original guideline document).

The GDG consensus was that patient satisfaction with treatment was the best overall indicator of treatment success since it includes those women who, while not on optimal treatment, may nevertheless have improved quality of life compared with before treatment.

Specific Considerations for This Guideline

The GDG made 'a priori' decisions regarding outcomes. For each outcome, it defined thresholds for clinically important differences (also known as 'minimal important difference' [MID]) for all outcome measures which are summarised here:

- For the outcome 'Patient satisfaction with treatment' the GDG agreed that, where possible, outcomes should be dichotomised into 'improved' and 'not improved' by combining categories, for example 'very improved' and 'improved'. The outcome statistic (RR) default definitions of MID were 0.75 and 1.25.

- For the outcome 'Self reported rate of absolute symptom reduction' the GDG agreed that a 50% reduction in symptoms constituted a clinically significant difference for both episodes of incontinence and episodes of urgency.
- For the outcome 'Continence status (zero episodes per day)' the GDG accepted that this was a valid definition in itself. Again, default definitions of MID for RR were used as above.
- For the outcome 'Incontinence-specific quality of life' the GDG agreed that only incontinence-specific quality of life should be used. The developers of these scales have published MIDs which can be used as the thresholds for clinically significant difference.
- For the outcome 'Adverse effects' the GDG agreed that this should vary from question to question. For example, for botulinum toxin A (BoNT-A), the need for self-catheterisation was specified as the single most important adverse effect. Default definitions of MID for relative risk were adopted as above.
- For the outcome 'Psychological outcomes' the GDG agreed that depression and anxiety were important outcomes. As with the incontinence-specific quality of life (I-QOL), an MID from the published literature would be used.
- For the outcome 'Clinical measures' the GDG agreed that post-void residual volume was the single most important of the different clinical measures used. In the absence of data, a default MID of 25% change in post-void residual volume was used. This meant that if the intervention or control led to an improvement or worsening of 25% of the baseline values then this was considered clinically meaningful for both patient and clinician.

Network Meta-Analysis

A network meta-analysis (NMA) can be undertaken where there is a comparison of multiple treatments. The approach is an extension of meta-analysis that includes multiple different pairwise comparisons across a range of interventions to treat one condition.

For this guideline, a hierarchical Bayesian NMA was undertaken to evaluate the effectiveness of antimuscarinic drugs for the treatment of overactive bladder. Trial populations were sufficiently homogenous to allow indirect comparisons of treatments that had not been directly evaluated as trials were identified that compared treatments with a common comparator. The analysis was strengthened by incorporating direct evidence from head-to-head trials as well as indirect comparisons from placebo-controlled trials. The output of the NMA was odds ratios and median probabilities of effectiveness with 95% credible interval ratios (comparable with confidence intervals). The probabilities of effectiveness were used to parameterise a new health economic model developed for this guideline update.

The NMA was undertaken in WinBugs® with additional expert support provided by the Technical Support Unit at NICE.

Incorporating Health Economics

The GDG prioritised a number of review questions where it was thought that economic considerations would be particularly important in formulating recommendations. Systematic searches for published economic evidence were undertaken for these questions. For economic evaluations, no standard system of grading the quality of evidence exists and included papers were assessed using a quality assessment checklist based on good practice in economic evaluation. Reviews of the relevant published health economic literature are presented alongside the clinical effectiveness reviews.

Health economic considerations were aided by original economic analysis undertaken as part of the development process. For this guideline the areas prioritised for economic analysis were:

- The cost effectiveness of antimuscarinic drugs for overactive bladder after conservative management has been unsuccessful (incorporating a network meta-analysis of evidence of effectiveness).
- The cost effectiveness of botulinum toxin A versus sacral nerve stimulation in the treatment of overactive bladder once pharmacological treatment has been unsuccessful.

A third analysis comparing surgical approaches for mid-urethral procedures in women undergoing their primary surgical tape procedure was considered. However, there was insufficient evidence of difference in effectiveness or cost between each type of procedure to undertake a health economic analysis.

Methods Used to Formulate the Recommendations

Expert Consensus

Informal Consensus

Description of Methods Used to Formulate the Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Women's and Children's Health (NCC-WCH) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

See the full version of the original guideline document (see the "Availability of Companion Documents" field) for the methodology for the 2006 version of this guideline.

The guideline was developed by a multi-professional and lay working group (the Guideline Development Group [GDG]) convened by the NCC-WCH. The membership is listed above. Staff from the NCC-WCH provided support for the guideline development process by undertaking systematic searches, retrieval and appraisal of the evidence and health economic modelling, and wrote successive drafts of the guideline.

This guidance was commissioned by NICE and developed in accordance with the guideline development process outlined in the 2009 edition of The Guidelines Manual (see the "Availability of Companion Documents" field).

In accordance with NICE's Equality Scheme, ethnic, and cultural considerations and factors relating to disabilities have been considered by the GDG throughout the development process and specifically addressed in individual recommendations where relevant. Further information is available from: www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp .

This guidance is a partial update of NICE clinical guideline 40 (published October 2006) and will replace it. For further information refer to Appendices A and D in the full version of the original guideline document.

Evidence to Recommendations

For each review question recommendations for clinical care were derived using, and linked explicitly to, the evidence that supported them. In the first instance, informal consensus methods were used by the GDG to agree short clinical and, where appropriate, cost effectiveness evidence statements which were presented alongside the evidence profiles.

Statements summarising the GDG's interpretation of the evidence and any extrapolation from the evidence used to form recommendations were also prepared to ensure transparency in the decision-making process. The criteria used in moving from evidence to recommendations were:

- Relative value placed on the outcomes considered
- Consideration of clinical benefits and harms
- Consideration of net health benefits and resource use
- Quality of the evidence
- Other considerations (including equalities issues)

In areas where no substantial clinical research evidence was identified, the GDG members considered other evidence-based guidelines and consensus statements or used their collective experience to identify good practice. The health economics justification in areas of the guideline where the use of National Health Service resources (interventions) was considered was based on GDG consensus in relation to the likely cost effectiveness implications of the recommendations. The GDG members also identified areas where evidence to answer their review questions was lacking and used this information to formulate recommendations for future research.

Towards the end of the guideline development process, formal consensus methods (voting) were used to consider all the clinical care recommendations that had been drafted previously.

Specific Considerations for This Guideline

Formal Consensus Voting

A formal consensus approach was used where it was agreed that a recommendation was required, but where the GDG was unable to reach a conclusion using discussion alone.

Methods

The formal consensus approach involved a series of action statements relating to management or treatment under review being drafted by the NCC-WCH technical team. These were collated into a consensus questionnaire. The GDG members were asked to independently complete the questionnaire stating their level of agreement ('strongly agree' to 'strongly disagree') with each statement and provide comments on where statements should be amended. The results of the voting were collated by the technical team. If 70% or more of the GDG members agreed or

disagreed with a statement then consensus was reached. If there was no consensus the statement could be adapted based on comments and presented for a second round of voting, applying the same majority threshold. This process would go on until consensus was reached, at which point the statements were then used to draft recommendations. These were discussed and ratified at a subsequent GDG meeting.

Rating Scheme for the Strength of the Recommendations

Strength of Recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group (GDG) makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the GDG is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

Interventions That Must (or Must Not) Be Used

The GDG usually uses 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally 'must' (or 'must not') is used if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Interventions That Should (or Should Not) Be Used – a 'Strong' Recommendation

The GDG uses 'offer' (and similar words such as 'refer' or 'advise') when confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. Similar forms of words (for example, 'Do not offer…') are used when the GDG is confident that an intervention will not be of benefit for most patients.

Interventions That Could Be Used

The GDG uses 'consider' when confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

Note: The National Institutes for Health and Care Excellence (NICE) began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of 'The guidelines manual' (January 2009). This does not apply to any recommendations shaded in grey in the original guideline document and ending [2006]. In particular, for recommendations labelled [2006] the word 'consider' may not necessarily be used to denote the strength of the recommendation.

Cost Analysis

Incorporating Health Economics

The aims of the health economic input to the guideline were to inform the Guideline Development Group (GDG) of potential economic issues relating to urinary incontinence and to ensure that recommendations represented a cost effective use of healthcare resources. Health economic evaluations aim to integrate data on benefits (ideally in terms of quality-adjusted life years [QALYs]), harms, and costs of different care options.

Health economic considerations were aided by original economic analysis undertaken as part of the development process. For this guideline the areas prioritised for economic analysis were:

- The cost effectiveness of antimuscarinic drugs for overactive bladder after conservative management has been unsuccessful (incorporating a network meta-analysis of evidence of effectiveness).
- The cost effectiveness of botulinum toxin A versus sacral nerve stimulation in the treatment of overactive bladder once pharmacological treatment has been unsuccessful.

A third analysis comparing surgical approaches for mid-urethral procedures in women undergoing their primary surgical tape procedure was considered. However, there was insufficient evidence of difference in effectiveness or cost between each type of procedure to undertake a health economic analysis.

See Appendix N in the full version of the original guideline document for details on the cost effectiveness of overactive bladder drugs for wet overactive bladder with incontinence. See Appendix O in the full version of the original guideline document for details on overactive bladder

procedures – health economics (see the "Availability of Companion Documents Field").

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

See the full version of the original guideline document (see the "Availability of Companion Documents" field) for the methodology for the 2006 version of this guideline.

Stakeholder Involvement

Registered stakeholder organisations were invited to comment on the draft scope and the draft guideline. Stakeholder organisations were also invited to undertake a pre-publication check of the final guideline to identify factual inaccuracies. The Guideline Development group carefully considered and responded to all comments received from stakeholder organisations. The comments and responses, which were reviewed independently by the National Institute for Health and Care Excellence (NICE), are published on the NICE website.

The final draft was submitted to the Guideline Review Panel for review prior to publication.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate management of women with urinary incontinence (UI) and overactive bladder (OAB)

See the "Consideration of clinical benefits and harms" sections in the full version of the original guideline document for additional details about benefits of specific interventions.

Potential Harms

Percutaneous Posterior Tibial Nerve Stimulation (P-PTNS)

The reported incidence of adverse effects for P-PTNS was low compared with other interventions for overactive bladder (OAB). Reported adverse events in one study were ankle bruising, discomfort at needle site, and tingling in the leg.

Pharmacologic Treatments

Antimuscarinic drugs may work differently in particular patient groups, for example frail older women and women with multiple co-morbidities of any age. These drugs have differing affinities for antimuscarinic receptors within the brain and a variable ability to cross the blood brain barrier. This has the potential for adverse effects on cognitive function, both in the short term, with a risk of acute confusional states, and in the longer term. This is particularly important in the context of absolute anticholinergic load, that is, the number of other medications the women is taking that have anticholinergic activity. These patient groups should still be offered treatment with these drugs for overactive bladder symptoms, but only after a full medication review.

Surgical Procedures for Stress Urinary Incontinence: Mid-urethral Tapes Approach

- A mid-urethral tapes procedure has two adverse effect profiles; one related to the device being used and other associated with the surgical approach.
- *Peri-operative adverse effects*. The difference in the angle of surgical incision used in the retropubic and transobturator approach means that the risk of iatrogenic damage caused by the surgery will vary. For example, the insertion of transobturator tapes presents a greater risk of vaginal wall injury than the retropubic approach, whereas there is a lower chance of bladder perforation. The classification of the severity of an adverse effect is often misinterpreted: for example, bladder perforation would be reported as a minor adverse event when seen in the short term but if it goes unnoticed the longer-term implications are more serious with mesh erosion into the bladder. The Guideline Development Group concluded that while one approach will show a reduction in risk for one specific adverse event, this is offset by another increased risk in another. The risks will be interconnected with the surgeon's skill in a given procedure. It is therefore important that a choice is available, taking into account the expected chance of adverse events. The procedure with which a surgeon is most familiar and has most experience is likely to be safer.
- This review identified four factors associated with a clinically and statistically significant likelihood of tape failure:
  - Body mass index (BMI) greater than 35
  - Maximum urethral closure pressure (MUCP) of 31 or more
  - Primary surgery versus secondary surgery
  - Preoperative anticholinergic medication use

See the "Consideration of clinical benefits and harms" and "Adverse effects" sections in the full version of the original guideline document for additional details on harms of specific interventions.

Contraindications

Contraindications

The Guideline Development Group felt an explicit recommendation should be made to prohibit the use of oxybutynin in frail older women because of the risk of impairment of daily functioning, which is common, as well as the less common risk of chronic confusion. In very rare cases, women can experience acute delirium, which is a serious adverse event that may require hospitalisation.

Qualifying Statements

Qualifying Statements

- This guidance represents the view of the National Institute for Health and Care Excellence (NICE), which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summaries of product characteristics of any drugs.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.
- Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If the patient is under 16, their family or carers should also be given information and support to help the child or young person to make decisions about their treatment. Healthcare professionals should follow the Department of Health's advice on consent . If someone does not have capacity to make decisions, healthcare professionals should follow the code of practice that accompanies the Mental Capacity Act and the supplementary code of practice on deprivation of liberty safeguards. In Wales, healthcare professionals should follow advice on consent from the Welsh Government .
- The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual

patients.

- This guideline recommends some drugs for indications for which they do not have a UK marketing authorisation at the date of publication, if there is good evidence to support that use. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or those with authority to give consent on their behalf) should provide informed consent, which should be documented. See the General Medical Council's Good practice in prescribing medicines – guidance for doctors for further information. Where recommendations have been made for the use of drugs outside their licensed indications ('off-label use'), these drugs are marked with a footnote in the recommendations.
- NICE has produced guidance on the components of good patient experience in adult National Health Service services. All healthcare professionals should follow the recommendations in Patient experience in adult National Health Service services.
- For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision.

Implementation of the Guideline

Description of Implementation Strategy

The National Institute for Health and Care Excellence (NICE) has developed tools to help organisations implement this guidance. These are available on the NICE Web site (see also the "Availability of Companion Documents" field).

Key Priorities for Implementation

The following recommendations have been identified as priorities for implementation.

History-taking and Physical Examination

- At the initial clinical assessment, categorise the woman's urinary incontinence (UI) as stress UI (SUI), mixed UI, or urgency UI/overactive bladder (OAB). Start initial treatment on this basis. In mixed UI, direct treatment towards the predominant symptom. [2006]

Assessment of Pelvic Floor Muscles

- Undertake routine digital assessment to confirm pelvic floor muscle contraction before the use of supervised pelvic floor muscle training for the treatment of UI. [2006, amended 2013]

Bladder Diaries

- Use bladder diaries in the initial assessment of women with UI or OAB. Encourage women to complete a minimum of 3 days of the diary covering variations in their usual activities, such as both working and leisure days. [2006]

Percutaneous Posterior Tibial Nerve Stimulation

- Do not offer percutaneous posterior tibial nerve stimulation for OAB unless:
  - There has been a multidisciplinary team review, and
  - Conservative management including OAB drug treatment has not worked adequately, and
  - The woman does not want botulinum toxin A[1] or percutaneous sacral nerve stimulation. [new 2013]

Absorbent Products, Urinals, and Toileting Aids

- Absorbent products, hand held urinals and toileting aids should not be considered as a treatment for UI. Use them only as:
  - A coping strategy pending definitive treatment
  - An adjunct to ongoing therapy
  - Long-term management of UI only after treatment options have been explored [2006]

General Principles When Using OAB Drugs

- Before OAB drug treatment starts, discuss with women:
  - The likelihood of success and associated common adverse effects, and
  - The frequency and route of administration, and

- That some adverse effects such as dry mouth and constipation may indicate that treatment is starting to have an effect, and
- That they may not see the full benefits until they have been taking the treatment for 4 weeks [new 2013]

Choosing OAB Drugs

- Offer one of the following choices first to women with OAB or mixed UI:
  - Oxybutynin (immediate release), or
  - Tolterodine (immediate release), or
  - Darifenacin (once daily preparation) [new 2013]
- If the first treatment for OAB or mixed UI is not effective or well-tolerated, offer another drug with the lowest acquisition cost[2]. [new 2013]

The Multidisciplinary Team (MDT)

- Offer invasive therapy for OAB and/or SUI symptoms only after a multidisciplinary team review. [new 2013]

Surgical Approaches for SUI

- When offering a surgical procedure discuss with the woman the risks and benefits of the different treatment options for SUI using the information in the "Information to facilitate discussion of risks and benefits of treatments for women with stress urinary incontinence" section of the original guideline document. [new 2013]

[1]At the time of publication (September 2013), most Botulinum toxin type A preparations did not have a UK marketing authorisation for this indication. Evidence was only available for the licensed Botulinum toxin A (BOTOX, Allergan) preparation.

[2]This could be any drug with the lowest acquisition cost from any of the drugs reviewed, including an untried drug from under "Pharmacological Treatment; Choosing OAB Drugs." The evidence review considered the following drugs: darifenacin, fesoterodine, oxybutynin (immediate release), oxybutynin (extended release), oxybutynin (transdermal), oxybutynin (topical gel), propiverine, propiverine (extended release), solifenacin, tolterodine (immediate release), tolterodine (extended release), trospium, and trospium (extended release). See Chapter 6 in the full version of the original guideline document for details (see the "Availability of Companion Documents" field").

Implementation Tools

Audit Criteria/Indicators

Clinical Algorithm

Mobile Device Resources

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Collaborating Centre for Women's and Children's Health. Urinary incontinence: the management of urinary incontinence in women. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Sep. 48 p. (Clinical guideline; no. 171).

Adaptation

Not applicable: The guideline was not adapted from another source.

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Guideline Committee

Guideline Development Group

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Financial Disclosures/Conflicts of Interest

All Guideline Development Group (GDG) members' potential and actual conflicts of interest were recorded on a declaration form provided by the National Institute for Health and Care Excellence (NICE) and are shown in Appendix C in the full version of the original guideline document (see the "Availability of Companion Documents" field). The form covered consultancies, fee-paid work, shareholdings, fellowships, and support from the healthcare industry. The Guideline Development Group leader and National Collaborating Centre for Women's and Children's Health executive director consider that the declarations made did not influence the recommendations developed.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: National Collaborating Centre for Women's and Children's Health. Urinary incontinence: the management of urinary incontinence in women. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Oct. 221 p.

Guideline Availability

Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .

Availability of Companion Documents

The following are available:

- Urinary incontinence: the management of urinary incontinence in women. Full guideline. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Sep. 388 p. (Clinical guideline; no. 171). Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Care Excellence (NICE) Web site .
- Urinary incontinence: the management of urinary incontinence in women. Appendices A-V (excluding H). London (UK): National Institute for Health and Care Excellence (NICE); 2013 Sep. 706 p. (Clinical guideline; no. 171). Electronic copies: Available in PDF from the NICE Web site .
- Urinary incontinence: the management of urinary incontinence in women. Appendix H. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Sep. 793 p. (Clinical guideline; no. 171). Electronic copies: Available in PDF from the NICE Web site .
- Urinary incontinence: the management of urinary incontinence in women. Baseline assessment tool. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Sep. (Clinical guideline; no. 171). Electronic copies: Available from the NICE Web site .
- Urinary incontinence: the management of urinary incontinence in women. Clinical audit tool. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Sep. (Clinical guideline; no. 171). Electronic copies: Available from the NICE Web site .
- Urinary incontinence: the management of urinary incontinence in women. Costing statement. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Sep. 10 p. (Clinical guideline; no. 171). Electronic copies: Available in PDF from the NICE Web site .
- Urinary incontinence in women. Academic detailing aid. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Sep. 4 p. (Clinical guideline; no. 171). Electronic copies: Available from the NICE Web site .
- Urinary incontinence: Norwegian stress and urge incontinence questionnaire SUIQQ. Norway: Norwegian UroGynaecological Group. 2013 Sep. 5 p. Electronic copies: Available in PDF from the NICE Web site .
- Urinary incontinence in women overview. NICE pathway. London (UK): National Institute for Health and Clinical Excellence (NICE); 2013 Sep. (Clinical guideline; no. 171). Electronic copies: Available from the NICE Web site .
- The guidelines manual 2009. London (UK): National Institute for Health and Care Excellence (NICE); 2009 Jan. Electronic copies: Available in PDF from the NICE Archive Web site .

Patient Resources

The following is available:

- Managing urinary incontinence in women. Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Sep. (Clinical guideline; no. 171). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available for download as a Kindle or EPUB ebook from the NICE Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide

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NGC Status

This NGC summary was completed by ECRI on March 30, 2009. This summary was updated by ECRI Institute on May 26, 2009, following the U.S. Food and Drug Administration advisory on Botox, Botox Cosmetic (Botulinum toxin Type A), and Myobloc (Botulinum toxin Type B). This NGC summary was updated by ECRI Institute on August 17, 2009, following the updated FDA advisory on Botox and Botox Cosmetic (Botulinum toxin Type A), and Myobloc (Botulinum toxin Type B). This NGC summary was updated by ECRI Institute on November 27, 2013.

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